DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857



#12

Re: FRAGMIN®
Docket No. 95E-0055

MAY 15 1995

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,303,651, filed by Pharmacia Aktiebolag, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for FRAGMIN®, the human drug product claimed by the patent.

The total length of the regulatory review period for FRAGMIN® is 3,555 days. Of this time, 2,832 days occurred during the testing phase and 723 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 31, 1985.

   The applicant did not state an Investigational New Drug application (IND) effective date, stating that foreign studies were used in lieu of an IND. However, FDA records indicate that certain studies material to the approval of the product were conducted under IND 25,924. Therefore, the IND effective date was March 31, 1985, which was thirty days after FDA receipt of IND 25,924.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: December 30, 1992.

   The applicant claims February 28, 1993, as the date the New Drug Application (NDA) for FRAGMIN® (NDA 20-287) was initially submitted, whereas it is actually the filing date. FDA records indicate that NDA 20-287 was refused to file on September 25, 1992. The correct resubmission date for NDA 20-287 is December 30, 1992, which was the date the resubmission was actually received by the agency. Therefore, the NDA initial submission date for NDA 20-287 is December 30, 1992, the same as the resubmission date.

3. The date the application was approved: December 22, 1994.

FDA has verified the applicant's claim that NDA 20-287 was approved on December 22, 1994.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

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